

United States ex rel. Ortolano v. Amin Radiology

United States District Court for the Middle District of Florida, Ocala Division

January 28, 2015, Decided; January 28, 2015, Filed

Case No. 5:10-cv-583-Oc-PRL

Reporter

2015 U.S. Dist. LEXIS 9724

UNITED STATES OF AMERICA and STATE OF FLORIDA ex rel. CHARLES ORTOLANO, Plaintiffs, -vs- AMIN RADIOLOGY d/b/a CITRUS DIAGNOSTIC CENTER, Defendant.

Prior History: [United States ex rel. Ortolano v. Amin Radiology](#), 2013 U.S. Dist. LEXIS 143206 (M.D. Fla., Oct. 3, 2013)

Core Terms

scans, certification, regulations, provider, false claim, supervision, licensing, condition of payment, reimbursement, requirements, procedures, services, diagnostic test, personnel, nuclear, conditions, matter of law, motions, false certificate, medicine, new trial, radiographers, technologists, Diagnostic, contractor, Radiology, license law, tests, performing, licensure

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Judges: Wm. Terrell Hodges, UNITED STATES DISTRICT JUDGE.

Opinion by: Wm. Terrell Hodges

Opinion

ORDER GRANTING DEFENDANT'S MOTION FOR JUDGMENT AS A MATTER OF LAW

This *qui tam* False Claims Act case was tried to a jury and resulted, in part, in a verdict awarding damages to the Plaintiff. The case is now before the Court on Defendant Amin Radiology d/b/a Citrus Diagnostic Center's ("Amin's") post trial [Rule 50\(b\)](#) Motion for Judgment as [*2] a Matter of Law (Doc. 102), and Alternative [Rule 59](#) Motion for New Trial (Doc. 103). Relator Charles Ortolano has filed timely responses to both motions (Docs. 113-114), and with leave of Court, Amin has filed reply briefs (Docs. 120-121). A hearing has been held and the motions are both ripe for disposition.

Upon due consideration, the Court finds that the motion for judgment as a matter of law is due to be granted, and the motion for new trial is due to be conditionally denied. [See Fed. R. Civ. P. 50\(c\)\(1\)](#).

Background and Procedural History

Mr. Ortolano filed a *qui tam* action under the False Claims Act, [31 U.S.C. § 3729, et seq.](#) ("FCA"), and the Florida False Claims Act, [Fla. Stat. §§ 68.081 et seq.](#), alleging that Amin, his former employer, a health care provider, violated both Acts by filing false claims for reimbursement under Medicare Part B, Medicaid, and Tricare.¹ The claims fell into four categories: (1) that Amin improperly classified its Dunnellon facility as an Independent Diagnostic Testing Facility; (2) that Amin improperly submitted claims for

¹ The original complaint was filed under seal on November 3, 2010 (Doc. 1). After the United States declined to intervene, Mr. Ortolano filed an amended complaint, also under seal (Doc. 7). The United States again declined to intervene, and the case was unsealed (Doc. 11).

MRI scans performed by an unlicensed technician at its Dunnellon facility; (3) that Amin improperly submitted claims for MRI scans with contrast dye injections at the Dunnellon facility without the proper [*3] level of supervision; and (4) that Amin improperly submitted claims for combination PET/CT scans performed at its Crystal River facility by general radiographers who did not hold the necessary license or certification to perform those procedures. The first claim was dismissed by the Court during pretrial motion practice. The second claim was dismissed by the Court during trial under *Fed. R. Civ. P. 50(a)*. The third claim was resolved by the jury in favor of Amin. There are no remaining disputes concerning any of those matters. The *Rule 50(b)* motion addressed by this Order involves only the jury verdict for the Plaintiff on the claim relating to combination PET/CT scans performed at Amin's Crystal River facility.

On May 9, 2014, at the end of a week long trial, the jury returned its verdict (Doc. 92), finding in favor of Mr. Ortolano on his contention that Amin made false claims to the United States and/or to the State of Florida seeking payment for [*4] combination PET/CT scans performed at the Crystal River facility by general radiographers rather than nuclear radiologic technologists.² The jury further found that Amin had submitted 426 such claims for payment, and that the total amount of damages attributable to Amin's submission of these claims was \$490,138.31 (*Id.*).

The PET/CT scan claim required interpretation of [Fla. Stat. § 468.302\(3\)](#), a part of the State's licensure and certification scheme, with specific reference to personnel who are authorized to perform nuclear medicine procedures such as combination PET/CT scans in Florida. Mr. Ortolano contended that certified nuclear medicine technologists were required to perform the entirety of the PET/CT scans, whereas Amin argued that general radiographers were permitted to perform all aspects of the scan other than the ordering, storage, and injection of the radioactive isotopes at [*5] the outset of the procedure. This issue of statutory interpretation was hotly contested by the Parties, and there was no legal authority on point to provide any guidance to the Court.

Because the interpretation of this statute was a question of law, the Court heard testimony outside the presence of the jury from James Futch, an environmental administrator with the Florida Department of Health, the agency responsible

for promulgating and enforcing all of the regulations regarding nuclear medicine technologists and certifications for CT, PET, and MRI scans. Mr. Futch testified that the uniform interpretation, application, and enforcement of the statute by the Department of Health is that only a nuclear medicine technologist is authorized in Florida to perform the entirety of a PET/CT scan. Relying on this uncontradicted testimony, the Court gave deference to the state agency's interpretation of [Fla. Stat. § 468.302\(3\)](#), found that interpretation to be reasonable, and held, as a matter of law, that at all times material to this case under the licensing and certification laws of Florida, only a licensed or certified nuclear medicine technologist was authorized to conduct a PET/CT scan. The Court so instructed [*6] the jury as a part of its final charge (Doc. 93).

In order to avoid multiple judgments and piecemeal appeals, the Court withheld the entry of judgment on the verdict in favor of the Plaintiff, and directed the Parties to file appropriate motions and supporting memoranda addressing their respective positions on unresolved issues concerning the determination of civil penalties to be assessed under [31 U.S.C. § 3729\(a\)\(1\)](#), the percentage of the total recovery to be allocated to Mr. Ortolano pursuant to [31 U.S.C. § 3730\(d\)\(2\)](#), and attorney's fees and costs to be awarded to Mr. Ortolano (Doc. 96). Mr. Ortolano filed several briefs and motions on these issues (Docs. 104-106). During this same time period, Amin filed its pending motions under *Fed. R. Civ. P. 50(b)* and *59(a)*, and the Court stayed Amin's responses to Mr. Ortolano's papers until the Court could resolve the *Rule 50(b)* and *59(a)* motions (Doc. 107).

The Court then heard oral argument on Amin's motions for judgment as a matter of law and for new trial (Doc. 125). At the conclusion of the hearing, the Court took the motions under advisement. Because the Court will now resolve both motions through the present order, and in the hope of simplifying any appellate proceedings, the Court will first direct the Clerk to enter [*7] judgment on the verdict for the Plaintiff, trebled in amount pursuant to [31 U.S.C. § 3729\(a\)\(1\)](#) and [Fla. Stat. § 68.082\(2\)\(g\)](#). The present order will then vacate that judgment and, in accordance with *Fed. R. Civ. P. 50(b)*, direct the entry of judgment in favor of Amin. Mr. Ortolano's pending motions concerning attorney's fees, penalties, and allocation of the percentage of total recovery will be rendered moot and will not be given further consideration unless and until this order is reversed and the judgment for the Plaintiff is reinstated.

² Testimony at trial — obviously credited by the jury — was to the effect that Mr. Ortolano was a certified nuclear medicine radiologic technologist who injected patients undergoing combination PET/CT scans with the necessary levels or dosages of radioactive isotopes, and that general radiographers would then complete the scans.

The Rule 50(b) Motion for Judgment As a Matter of Law**I. Standard of Review**

The standard for granting a renewed motion for judgment as a matter of law under *Rule 50(b)* is the same as the standard for granting a pre-verdict motion under *Rule 50(a)*. [Hubbard v. BankAtlantic Bancorp, Inc.](#), 688 F.3d 713, 724 (11th Cir. 2012) (citations omitted). Thus, under *Rule 50*, a “district court should grant judgment as a matter of law when the plaintiff presents no legally sufficient evidentiary basis for a reasonable jury to find for [plaintiff] on a material element of [plaintiff’s] cause of action.” [Pickett v. Tyson Fresh Meats, Inc.](#), 420 F.3d 1272, 1278 (11th Cir. 2005) (citations omitted). Stated differently, a district court should grant a *Rule 50(b)* motion “only if the evidence is so overwhelmingly in favor of the moving party that a reasonable jury could not arrive at a contrary verdict.” [Middlebrooks v. Hillcrest Foods, Inc.](#), 256 F.3d 1241, 1246 (11th Cir. 2001). The Court “must review [*8] all of the evidence in the record and must draw all reasonable inferences in favor of the nonmoving party.” [Walker v. NationsBank of Fla., N.A.](#), 53 F.3d 1548, 1555 (11th Cir. 1995). “When a court considers a motion for judgment as a matter of law — even after the jury has rendered a verdict — only the sufficiency of the evidence matters. The jury’s findings are irrelevant.” [Connelly v. Metropolitan Atlanta Rapid Transit Authority](#), 764 F.3d 1358, 1363 (11th Cir. 2014) (quoting [Hubbard](#), 688 F.3d at 716).

II. Discussion

Amin raises two grounds in support of its *Rule 50(b)* motion. First, that Mr. Ortolano failed to prove that compliance with [Fla. Stat. § 468.302\(3\)](#), the state statute governing licensing of personnel authorized to perform PET/CT scans, is a condition of payment as distinguished from a condition of participation relating to such procedures by Medicare, Medicaid, or Tricare, and therefore Amin is not liable under the False Claims Act.³ Second, Amin renews its argument made at trial — which the Court rejected — that its PET/CT claims were neither false nor fraudulent as a matter of law because Amin’s use of general radiographers to perform PET/CT scans is not prohibited by Florida law. It is unnecessary to revisit that issue, however, because it is irrelevant to Amin’s first argument which the Court finds to be both persuasive and dispositive.

A. The False Claim Theory

With specific reference to government reimbursement of medical expenses as the underlying basis for a suit under the False Claims Act, there are two ways in which a claim for reimbursement by a health care provider may be condemned as false or fraudulent, and therefore actionable, under the Act. The first — known as “factually false” or “direct” fraud — occurs when a provider submitting a claim supplies “an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided.” [Mikes v. Straus](#), 274 F.3d 687, 697 (2nd Cir. 2001). In other words, the party falsely “bills for something it did not provide.” [United States ex rel. Kirk v. Schindler Elevator Corp.](#), 601 F.3d 94, 113 (2d Cir. 2010), *rev’d on other grounds*, [U.S. , 131 S. Ct. 1885, 179 L. Ed. 2d 825 \(2011\)](#). In such cases, application of the False Claims Act is fairly straightforward. [*10] *Id.* at 114. *See also* [United States ex rel. Conner v. Salina Regional Health Center, Inc.](#), 543 F.3d 1211, 1217 (10th Cir. 2008). The second, known as a “false certification theory,” occurs “when the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment.” [United States v. Medquest Assocs., Inc.](#), 711 F.3d 707, 714 (6th Cir. 2013) (quoting [United States ex rel. Wilkins v. United Health Grp., Inc.](#), 659 F.3d 295, 305 (3rd Cir. 2011)).

Mr. Ortolano argues (and has argued throughout the prosecution of the case) that Amin’s billing for combination PET/CT scans was a factual or direct fraud. His argument goes like this: Medicare Part B, the portion of the program that covers the costs of physician services, supplies, and tests, prohibits reimbursement of procedures or services unless they are “reasonable and necessary for the diagnosis and treatment of illness or injury” [42 U.S.C. § 1395y\(a\)\(1\)\(A\)](#). *See also* [42 C.F.R. § 411.15\(k\)\(1\)](#). Mr. Ortolano contends that Medicare has mandated that diagnostic tests such as PET/CT scans involving the injection of nuclear material must be *in toto* performed by nuclear medicine technologists, and such tests performed by others are not considered reasonable and necessary. Because it is undisputed that Amin permitted general radiographers to perform PET/CT scans after Mr. Ortolano had injected the radioactive isotopes, (and it is presumed for purposes of this motion that general radiographers [*11] were not qualified

³ In undertaking an analysis of the case, it is essential [*9] to bear in mind that it is not an action seeking to enforce Medicare or to pursue any claim or cause of action predicated upon Medicare, Medicaid, or Tricare. It is, rather, a suit brought under the False Claims Act, and is governed by the law applicable to that Act. The fact that there may have been a violation of the laws governing Medicare, Medicaid, or Tricare is not enough, standing alone, to sustain a cause of action under the False Claims Act. *See* [Mikes v. Straus](#), 274 F.3d 687, 697 (2nd Cir. 2001).

personnel under Florida law), Mr. Ortolano concludes that the PET/CT scans were not "necessary," were unreimbursable as a matter of law, and Amin's submission of such procedures for payment constituted direct fraud.⁴

Mr. Ortolano's theory is not supported by any binding or persuasive legal precedent.⁵ Rather, he relies solely on a four-page excerpt from a Medicare Program Integrity Manual, Chapter 13 - Local Coverage Determinations. Specifically, Mr. Ortolano cites to § 13.5.1, which states, in relevant part, that "An [*12] item or service may be covered by a contractor LCD if: It is reasonable and necessary under [1862\(a\)\(1\)\(A\) of the Act](#). . . . Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is: Ordered and furnished by qualified personnel." (Doc. 56-9, pp. 4-5). But this manual also fails to support Mr. Ortolano's theory of the case.

The four-page excerpt of the manual [*13] submitted by Mr. Ortolano (Doc. 56-9) does not define "contractor," "Local Coverage Determination," or "qualified personnel" and does not address or mention PET scans, CT scans, or any combination of the two. However, the Centers for Medicare and Medicaid Services ("CMS"), the entity created by the Department of Health and Human Services to administer Medicare and Medicaid, and the entity which issued the Medicare Program Integrity Manual, does provide definitions for these terms. A "contractor" is defined as "[a]n entity that has an agreement with CMS or another funding agency to

perform a project."⁶ "Local Coverage Determination" is defined as "a decision by a Medicare Contractor whether to cover a particular service or item on a contractor-wide basis in accordance with [Section 1862\(a\)\(1\)\(A\)](#) of the Social Security Act (*i.e.*, a determination as to whether the service is reasonable and necessary)."⁷ A Medicare Contractor is defined as "a Medicare Part A Fiscal Intermediary, a Medicare Part B Carrier, or a Medicare Durable Medical Equipment Regional Carrier."⁸ A Medicare Part B Carrier is defined as "a Medicare contractor that administers the Medicare Part B benefits for a given region."⁹ Amin, as a physician practice [*14] group, does not fall within any of these definitions. Thus, it does not appear that this portion of the Medicare Program Integrity Manual applies to Amin or to the procedures at issue in this Order.¹⁰

The Court is further persuaded by the fact that the Medicare regulations themselves do not address the question of qualified personnel when defining whether a diagnostic test performed by a physician practice group such as Amin is "reasonable and necessary." Rather, the regulations governing diagnostic tests, which would include PET/CT scans, are considered "reasonable and necessary" when they are "furnished under the appropriate level of supervision by a physician." [42 C.F.R. § 410.32\(b\)\(1\)](#). The regulation is limited to a discussion of the appropriate level of supervision; there is no discussion whatsoever of the qualifications or

⁴ There has never been any argument or evidence that any of the PET/CT scans carried out by Amin were medically unnecessary in the sense that they were not ordered by qualified physicians or were not reasonably needed for diagnostic purposes. Nor is there any evidence that the resulting scans were medically faulty or unreliable in any way simply because they were completed by general radiographers rather than nuclear medicine technologists. Nor is there any evidence that any patient was ever injured or harmed in any way by the manner in which the scans were carried out. Similarly, there is no evidence that the fees charged by Amin were unreasonable or excessive.

⁵ The two decisions Mr. Ortolano cites are inapposite. [United States ex rel. Walker v. R&F Properties of Lake County, Inc.](#), 433 F.3d 1349 (11th Cir. 2005) involved the payment of claims for the services of a nurse practitioner that were not "incident to the services of a physician" as that phrase was defined by Medicare regulations. Mr. Ortolano merely cites to [Walker](#) for the general proposition that "[m]edicare claims may be false if they claim reimbursement for services or costs that either are not reimbursable or were not rendered as claimed." [433 F.3d at 1356](#). The second decision, [United States v. Calhoun](#), 97 F.3d 518 (11th Cir. 1996), involved an appeal from a criminal conviction for mail fraud and for signing false Medicare cost reports claiming expenses that were not reimbursable. Neither decision defines the term "reasonable and necessary," or discusses whether the use of unqualified personnel to perform services renders a claim not reimbursable.

⁶ <https://www.cms.gov/apps/glossary/default.asp?Letter=C&Language=English>

⁷ <https://www.cms.gov/apps/glossary/default.asp?Letter=L&Language=English>

⁸ <https://www.cms.gov/apps/glossary/default.asp?Letter=M&Language=English>

⁹ *Id.*

¹⁰ It should also be noted that even if the subject manual applied, it is not a formal regulation and, therefore, is not entitled to any deference that a regulation would command. See [Medquest](#), 711 F.3d at 716.

licensing requirements of the persons performing the diagnostic tests.¹¹

In contrast, the regulation governing Independent Diagnostic Testing Facilities ("IDTF"),¹² which Amin's Citrus Center is not, clearly states that nonphysician personnel who perform diagnostic [*16] tests

must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State health or education department. In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body. The IDTF must maintain documentation available for review that these requirements are met

[42 C.F.R. § 410.33\(c\)](#). The absence of similar language with respect to nonphysician personnel performing diagnostic tests at physician practice groups like Amin's Citrus Center is telling. Such silence can only be interpreted to mean that Medicare did not intend to include the licensing and certification requirements of non-physician personnel in the definition of reimbursable "reasonable and necessary" procedures performed by a physician practice group. See also Medquest, 711 F.3d at 716 (noting that a Medicare contractor's local medical review policies - now known as Local Coverage Determinations — "does not purport to supplement the 'reasonable and necessary' conditions contained in [§ 410.32](#)").

The Court's conclusion is expressly buttressed by the administrative history of the Medicare regulations. At the time these regulations were enacted, specifically [42 C.F.R. §§ 410.32](#) and [410.33](#), the Department of Health and Human Services, Health Care Financing Administration stated:

We believe it to be entirely appropriate to require the technologists who perform tests in IDTFs to possess appropriate credentialing while not imposing the same requirements on hospitals that must meet accreditation standards imposed by governmental and other bodies or on physicians' offices that operate under the authority of the physician's State licensure.

62 Fed. Reg. 59,048.

Indeed, Mr. Ortolano's [*18] argument concerning the certification of personnel performing PET/CT scans would be much more compelling if the PET/CT scans were being performed at an enrolled Independent Diagnostic Testing Facility rather than at an enrolled physician practice group. The Medicare regulations governing diagnostic tests explicitly require technicians working at IDTFs to have all necessary certifications and licenses, whereas the regulations do not so specify with respect to employees of physician practice groups. However, Amin's Crystal River facility was clearly enrolled and operated exclusively as a physician practice group. The Court therefore cannot say that there was any direct or factual fraud in this case.

In sum, the Court concludes that Mr. Ortolano's legal theory misapplies the phrase "reasonable and necessary" with respect to factually or directly fraudulent claims for reimbursement. With the exception of the level of supervision requirements contained in [42 C.F.R. § 410.32](#), the Court concludes that "reasonable or necessary" diagnostic tests performed at physician practice groups means those that are medically necessary and actually performed. Again, there is no evidence in this case that any of the PET/CT [*19] scans performed by Amin were medically unnecessary or were not performed at all, and it is those types of "per se false" claims that are encompassed under a "direct fraud" theory.

¹¹ In his response in opposition, Mr. Ortolano also argues that the PET/CT scans were not reasonable or necessary because they were not [*15] performed under the appropriate level of physician supervision as required by [42 C.F.R. § 410.32\(b\)\(1\)](#). This theory was never presented to the jury, and was waived. See Fed. R. Civ. P. 49(a)(3). Rather, the PET/CT scans claims were only submitted to the jury under the theory that they were performed by persons not authorized, licensed, or certified by Florida to conduct such procedures. See Verdict, Doc. 92. See also Joint Pretrial Statement, Doc. 58, p. 3 ("Relator intends to show that Amin Radiology knowingly submitted claims to the United States and to the State of Florida to perform nuclear procedures. Relator intends to show that Dr. Amin and Dr. Fisher were aware of this practice, failed to get the individuals performing the procedures the necessary licenses, and therefore also failed to adequately supervise the PET/CT procedure.") In other words, Mr. Ortolano claimed only that the failure to secure licenses for persons performing the PET/CT scans was itself a lack of "supervision," not that there was a failure to supervise the tests themselves.

¹² "An IDTF is a facility that is separate and independent of a hospital or a physician's office, where patients go to obtain [*17] certain x-rays, scans, and other imaging and diagnostic tests that are ordered by the patients' physicians." United States ex rel. Hobbs v. MedQuest Assocs., Inc. ("Hobbs I"), 702 F. Supp. 2d 909, 912 (M.D. Tenn. 2010). An IDTF may be a fixed location, a mobile entity, or an individual nonphysician practitioner. [42 C.F.R. § 410.33\(a\)\(1\)](#). An IDTF must have one or more supervising physicians who are responsible for providing general supervision of the procedures at the facility, and for procedures requiring direct or personal supervision, the IDTF's supervising physician must personally furnish that level of supervision. [42 C.F.R. §§ 410.33\(b\)\(1\), \(2\)](#).

The Court thus concludes as a matter of law that the claims submitted by Amin for reimbursement of its fees or expenses in conducting PET/CT scans at its physician practice group in Crystal River were not a direct fraud under the False Claims Act. This is, and always has been, at most, a “false certification” case.¹³

B. The False Certification Theory - Express vs. Implied

There are two ways to establish a false certification theory of liability under the FCA. The first is through an express certification, whereby “an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds.” [United States ex rel. Wilkins v. United Health Group, Inc.](#), 659 F.3d 295, 305 (3d Cir. 2011). In other words, an express certification occurs when the defendant actually signs or otherwise certifies compliance with some law or regulation that is identified on the face of the claim submitted. [Medquest](#), 711 F.3d at 714. The Eleventh Circuit Court of Appeals has adopted the express certification theory of liability. See [United States ex rel. McNutt v. Haleyville Med. Supplies, Inc.](#), 423 F.3d 1256, 1259 (11th Cir. 2005).

The second species of certification fraud under the False Claims Act is known as implied false certification liability, “which attaches when a claimant seeks and makes [*21] a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment.” [Wilkins](#), 659 F.3d at 305 (emphasis supplied). Courts do not look to the defendant’s actual statements; rather, the analysis focuses on the underlying statutes or regulations themselves to ascertain whether they make compliance a prerequisite to government reimbursement. [United States ex rel. Conner v. Salina Regional Health Center, Inc.](#), 543 F.3d 1211, 1218 (10th Cir. 2008). “[A]n implied false certification theory of liability is premised ’on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing

federal rules that are a precondition to payment.’” *Id.* (quoting [Mikes](#), 274 F.3d at 696). See also [Chesbrough v. VPA, P.C.](#), 655 F.3d 461, 468 (6th Cir. 2011) (holding that “liability can attach [under the FCA] if the claimant violates its continuing duty to comply with the regulations on which payment is conditioned.”) (quotations omitted). The implied certification theory is also viable in this Circuit.¹⁴ See [United States v. Keeler](#), 568 Fed. Appx. 783 (11th Cir. June 11, 2014); [United States ex rel. Freedman v. Suarez-Hoyos](#), 781 F. Supp. 2d 1270, 1278-79 (M.D. Fla. 2011). See also [Wilkins](#), 659 F.3d at 306 (citing [McNutt](#) for the proposition that the Eleventh Circuit has joined the majority of courts of appeals in recognizing implied false certification liability).

There is a conspicuous — and fatal — lack of evidence establishing that Amin ever made any written, express certification to Medicare, Medicaid, or Tricare that its PET/CT scans were performed in compliance with Florida licensing requirements. Mr. Ortolano did not offer into evidence any claim forms that were presented by Amin for payment that explicitly certified compliance with Florida licensure law, nor has he offered any provider or enrollment agreements containing any such certifications. And his reliance on a February 15, 2006 Medicare Certification Statement contained in CMS Form 855B is also misplaced. Mr. Ortolano has never offered that document into evidence either. Rather, the only references to CMS Form 855B are in a factual allegation contained in the Amended Complaint, see Doc. 12, ¶¶ 21, 46, and in this Court’s denial of Amin’s motion for summary judgment (Doc. 71, p. 3); but the Court’s acceptance of CMS Form 855B as a fact in ruling on a motion for summary judgment does not [*23] equate to an admission of evidence at a jury trial.

Even if the CMS Form 855B certification had been admitted into evidence at trial, it would not establish an express certification. See [Medquest](#), 711 F.3d at 714 (“The falsity of a claim is determined at the time of submission.”) (citing [United States ex rel. Quinn v. Omnicare, Inc.](#), 382 F.3d 432, 438-39 (3d Cir. 2004)); [United States ex rel. Clausen v. Lab.](#)

¹³ Mr. Ortolano’s final argument in attempting to sustain a direct fraud theory of liability relies on [Fla. Stat. § 409.907](#). The statute is entitled “Medicaid provider agreements,” and it states that “[e]ach provider agreement shall require the provider to comply fully with all state and federal laws pertaining to the Medicaid program, as well as all federal, state, and local laws pertaining to licensure, if required,” [Fla. Stat. § 409.907\(1\)](#). But this statute is of no aid to Mr. Ortolano for several reasons, not the least of which is the fact that there is no evidence of any “provider agreement” entered into by Amin. If there is one, it was not offered or received in evidence. Moreover, any such contract as described in the statute might [*20] be relevant to a false certification theory, but there is no authority that the submission of a form of claim that does not specifically warrant compliance with all applicable licensing laws but is arguably violative of an underlying contractual provision constitutes also a direct fraud in violation of the False Claims Act.

¹⁴ Amin has steadfastly argued that an implied certification theory of liability does not exist in the Eleventh Circuit. However, at the August 21, [*22] 2014 oral argument, counsel for Amin conceded that in light of the recent unpublished [Keeler](#) decision, which is persuasive precedent, such a theory of liability would now be viable in this Circuit.

[Corp. of America, Inc.](#), 290 F.3d 1301, 1311 (11th Cir. 2002) (“The submission of a claim is . . . the *sine qua non* of a False Claims Act violation.”). Mr. Ortolano has not argued or presented any evidence that Amin intended to violate any federal, state, or local laws at the time it applied for enrollment in Medicare. Moreover, the portion of the certification quoted in the Amended Complaint does not contain language conditioning payment on compliance with any particular law. [Id.](#) at 715.

Thus, the only manner in which Mr. Ortolano can prevail is by establishing that Amin made an implied certification to Medicare, Medicaid, and/or Tricare that its PET/CT scans were performed in accordance with Florida law, and that is the issue that was submitted to the jury.

The implied certification theory, as stated in the Court’s jury instructions and verdict form, was based on the assertion that Amin implicitly certified compliance with Florida’s licensing and certification laws for PET/CT scans every time [*24] that Amin submitted a claim for payment to Medicare, Medicaid, or Tricare. However, “[t]he False Claims Act does not create liability merely for a health care providers’ disregard of Government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe.” [Clausen](#), 290 F.3d at 1311. See also [United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.](#), 125 F.3d 899, 902 (5th Cir. 1997) (“[C]laims for services rendered in violation of a statute do not necessarily constitute false or fraudulent claims under the FCA.”); [United States ex rel. Hopper v. Anton](#), 91 F.3d 1261, 1266 (9th Cir. 1996) (“Violations of laws, rules, or regulations alone do not create a cause of action under the FCA.”).

Rather, to succeed on an implied certification theory, Mr. Ortolano must have presented sufficient evidence to the jury that Amin’s violation of Florida’s licensing laws with respect to PET/CT procedures was a condition of payment, as opposed to a condition of participation in the Medicare, Medicaid, or Tricare programs (which does not support an FCA claim). Stated differently, to prevail on his FCA claim, Mr. Ortolano had to prove that Medicare, Medicaid, and/or Tricare would not have paid Amin’s claims for PET/CT scans if the paying agency had known that Amin was not in full compliance with Florida’s licensing law. [*25] See [Medquest](#), 711 F.3d at 714; [Chesbrough](#), 655 F.3d at 468; [United States ex rel. Mastej v. Health Mgmt. Assocs., Inc.](#), 869 F. Supp. 2d 1336, 1343 (M.D. Fla. 2012). Here again there is no evidence that this was the case. One might speculate that Medicare, Medicaid, or Tricare would refuse payment under Mr. Ortolano’s theory of the case, but no

evidence to that effect was offered nor was it shown that such was not susceptible of proof.

C. Condition of Payment vs. Condition of Participation

Conditions of payment are “those which, if the government knew they were not being followed, might cause it to actually refuse payment.” [Conner](#), 543 F.3d at 1220. “Conditions of participation, as well as a provider’s certification that it has complied with those conditions, are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program.” [Conner](#), 543 F.3d at 1220; see also [Mikes](#), 274 F.3d at 701-02; [Baklid-Kunz v. Halifax Hosp. Medical Center](#), 2014 U.S. Dist. LEXIS 89357, 2014 WL 2968251 at * 5 (M.D. Fla. July 1, 2014). However, violations of a condition of participation do not form the basis of an FCA claim. [Medquest](#), 711 F.3d at 714. See also [United States ex rel. Gross v. AIDS Research Alliance-Chicago](#), 415 F.3d 601, 604 (7th Cir. 2005) (“An FCA claim premised upon an alleged false certification of compliance with statutory or regulatory requirements also requires that the certification of compliance be a condition of or prerequisite to government payment.”). Mr. Ortolano has not presented any evidence that compliance with [Florida Statute § 468.302\(3\)](#) is a condition of payment under Medicare, Medicaid, or [*26] Tricare. Nor has he made any cogent legal argument on this point.

Mr. Ortolano has not pointed to any Medicare, Medicaid, or Tricare statute or regulation that expressly conditioned payment on compliance with Florida licensing laws. See [United States ex rel. Steury v. Cardinal Health, Inc.](#), 735 F.3d 202, 207 n. 3 (5th Cir. 2013) (“[M]ost of the courts that have accepted the implied false certification theory have done so only where the government expressly conditioned payment on compliance with the underlying statute or regulation.”) (quoting John T. Boese, 1 Civil False Claims and Qui Tam Actions § 2.02(B)(3) (4th Ed. 2012)); [Mikes](#), 274 F.3d at 700 (“Specifically, implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid.”) (emphasis in original). As discussed above, the Medicare regulation governing diagnostic tests, [42 C.F.R. § 410.32](#) discusses levels of physician supervision. The regulation also requires the treating physician to order the diagnostic test, and establishes recordkeeping requirements. And unlike the regulations governing IDTF’s, see [42 C.F.R. § 410.33](#), which Amin’s Crystal River facility is not, the regulation governing diagnostic tests is notably silent with respect to licensing and certification [*27] requirements of the

personnel performing the tests. Cf. [Medquest, 711 F.3d at 715](#) (“[T]he natural reading of the relevant regulations supports only a conclusion that contrast testing is not reasonable and necessary if it is not performed under direct supervision by a physician.”).

Given this void in the regulations, Mr. Ortolano relies on the four-page excerpt from the Medicare Program Integrity Manual, which the Court has determined does not apply in this case, and on [Fla. Stat. § 409.907](#), the state Medicaid provision governing the contents of provider agreements. This statute, which does not mention any diagnostic tests or reference Florida’s licensing laws, at most establishes conditions of eligibility and participation in Medicaid.

Moreover, the Florida Radiological Personnel Certification Act, of which [Fla. Stat. § 468.302](#) is a part, does not mention or relate in any way to claims or payments under Medicare, Medicaid, or Tricare. Rather, the Act lists the certification and licensing requirements for persons authorized to operate radiation and nuclear medicine technology, lists grounds for disciplinary actions, and authorizes administrative and criminal penalties. See [Fla. Stat. §§ 468.302, 468.3101, 468.311, 468.3115](#).

No authority has been cited that would support any theory that compliance [*28] with state licensure laws is a condition of payment under Medicare, Medicaid, and/or Tricare.¹⁵ On the other hand, Amin points to several legal authorities which show that compliance with state laws is a condition of participation, not a condition of payment. See, e.g., [42 C.F.R. § 424.516\(a\)\(2\)](#) (stating that providers who enroll and maintain active enrollment status in Medicare must certify compliance with federal and state licensure, certification, and regulatory requirements, as required, based on the type of services provided); [42 C.F.R. § 482.11](#) (stating that a condition of participation for hospitals is compliance with federal, state, and local laws); [42 C.F.R. § 482.12](#) (same for home health services providers); [42 C.F.R. § 485.707](#) (same for clinics, rehabilitation agencies, and public health agencies); [42 C.F.R. § 418.116](#) (same for hospice providers). See also [United States ex rel. Escobar v. Universal Health Servs., Inc., 2014 U.S. Dist. LEXIS 40098, 2014 WL 1271757 \(D. Mass. Mar. 26, 2014\)](#)

(holding that purported violations of state law concerning qualifications and supervision of psychiatrists, psychologists, counselors, nurses, and other mental health staff are conditions of participation and cannot support an FCA claim); [United States ex rel. Woodruff v. Hawaii Pac. Health, 2007 U.S. Dist. LEXIS 37059, 2007 WL 1500275 at * 7-8 \(D. Haw. May 21 2007\)](#) (dismissing FCA claims where relator asserted that defendant violated Hawaii state licensing laws for nurse practitioners; the licensing laws were conditions of participation, not [*29] conditions of payment); [United States ex rel. Joslin v. Community Home Health of Maryland, Inc, 984 F. Supp. 374, 384-85 \(D. Md. 1997\)](#) (granting summary judgment in an FCA claim because compliance with state licensing requirements for home health care agencies is not a condition of payment, but rather a condition of participation in Medicare).

The Court finds these legal authorities persuasive, particularly in light of the complete absence of any statutory, [*30] regulatory, decisional, or other viable authority suggesting that a failure to comply with Florida’s licensing laws with respect to radiation and nuclear medicine testing is a condition of payment under Medicare, Medicaid, or Tricare. The only way to accept Mr. Ortolano’s theory of the case is “by weaving together isolated phrases from several sections in the complex scheme of Medicare regulations” as well as portions of Florida statutes. [Medquest, 711 F.3d at 715](#). As the Sixth Circuit succinctly stated “[t]his cut-and-paste approach is not supported by the structure of the regulatory scheme, and it is not reasonable to expect Medicare [Medicaid, or Tricare] providers to attempt such an approach to statutory interpretation in their efforts to comply with the FCA.” *Id.*

The Court therefore finds, as a matter of law, that compliance with [Fla. Stat. § 468.302](#) is, at most, a condition of participation, and not a condition of payment. As such, Mr. Ortolano’s FCA claim fails, and the jury’s verdict in favor of Mr. Ortolano cannot stand. Indeed, because compliance with this Florida law is a condition of participation only, the PET/CT scans claim should never have been submitted to

¹⁵ Mr. Ortolano cites solely to [McNutt, 423 F.3d 1256](#), which he asserts stands for the proposition that violations of conditions of participation can form the basis of an FCA claim. Mr. Ortolano reads [McNutt](#), which involved purported violations of the Anti-Kickback Statute, too broadly. The parties in [McNutt](#) agreed that failure to comply with the Anti-Kickback Statute “is a condition of payment by the Medicare program.” [423 F.3d at 1259](#). The [McNutt](#) court further held that liability under the FCA is only created where a “provider knowingly asks the Government to pay amounts it does not owe.” *Id.* (quoting [Clausen, 290 F.3d at 1311](#)). Here, even if Mr. Ortolano is right about the applicable law, there is no evidence that Amin knew that his claims for reimbursement were fraudulent and unlawful. Even the Court found it necessary to take testimony concerning the meaning and scope of the disputed Florida Statute.

the jury.¹⁶ Judgment as a matter of law is due to be entered in [*31] favor of Amin.

The Motion for New Trial

Rule 50(c) of the Federal Rules of Civil Procedure states:

If the court grants a renewed motion for judgment as a matter of law, it must also conditionally rule on any motion for a new trial by determining whether a new trial should be granted if the judgment is later vacated or reversed. The court must state the grounds for conditionally granting or denying the motion for a new trial.

Conditionally granting the motion for a new trial does not affect the judgment's finality; if the judgment is reversed, the new trial must proceed unless the appellate court orders otherwise. If the motion for a new trial is conditionally denied, the appellee may assert error in that denial; if the judgment is reversed, the case must proceed as the appellate court orders.

Fed. R. Civ. P. 50(c)(1), (2).

Amin argues in its *Fed. R. Civ. P. 59* alternative motion for a new trial that the Court gave three erroneous instructions [*32] to the jury at the conclusion of trial (Doc. 103). These erroneous instructions relate to: (1) the elements of an implied certification theory of liability, specifically condition of participation vs. condition of payment; (2) whether [Fla. Stat. § 468.302](#) prohibits general radiographers from performing PET/CT procedures; and (3) the calculation of damages.

Having reviewed the entirety of Amin's motion and reply, as well as Mr. Ortolano's response, the Court finds that the alternative motion for a new trial is due to be conditionally denied. Except for the issue of damages, the issues raised are questions of law which have already been determined in the Court's ruling on the renewed motion for judgment as a matter of law. With respect to the damages issue, the Court is unpersuaded by Amin's arguments, which the Court also rejected at trial. If this was a condition of payment case (which the Court has now ruled that it is not) then the Government would not have paid any portion of the disputed claims, and the measure of damages would necessarily be the entire amount paid to Amin for each procedure.

Thus if the Court of Appeals affirms this Court's order, there will be no new trial, and the judgment in favor [*33] of Amin that will be entered contemporaneously with this motion will stand. However, if the Court of Appeals reverses, this Court will simply reinstate the prior judgment on the jury's verdict in favor of the Plaintiff, or otherwise obey the mandate of the Court of Appeals if it concludes that some other course should be followed. If the judgment for the Plaintiff is reinstated, the Court will then address the remaining issues concerning attorney's fees, percentage of total recovery to be distributed to Mr. Ortolano, and civil penalties. In any event, there should be no need for a new trial.

Conclusion

Accordingly, upon due consideration, it is ORDERED as follows:

(1) The Clerk is directed to forthwith enter judgment on the jury verdict (Doc. 92, ¶ 12) in favor of the Plaintiffs United States of America and the State of Florida *ex rel.* Charles Ortolano and against the Defendant Amin Radiology, Inc. d/b/a Citrus Diagnostic Center in the amount of \$1,470,414.90 (consisting of the sum of \$490,138.31 trebled pursuant to [31 U.S.C. § 3729\(a\)\(1\)](#) and [Fla. Stat. § 68.082\(2\)\(g\)](#)), plus costs to be assessed according to law. The Court reserves ruling on additional civil penalties to be assessed under [31 U.S.C. § 3729\(a\)\(1\)](#) and the percentage of the Plaintiffs' recovery [*34] to be allocated to the Relator, Charles Ortolano, pursuant to [31 U.S.C. § 3730\(d\)\(2\)](#).

(2) Defendant Amin Radiology, Inc. d/b/a Citrus Diagnostic Defendant Center's Renewed *Rule 50(b)* Motion for Judgment as a Matter of Law (Doc. 102) is GRANTED.

(3) The Judgment entered by the Clerk pursuant to the directive given in paragraph (1) above is hereby VACATED AND SET ASIDE, and the Clerk is now directed to enter judgment in favor of the Defendant Amin Radiology, Inc. d/b/a Citrus Diagnostic Center and against the Plaintiffs United States of America and the State of Florida *ex rel.* Charles Ortolano, on all claims, the Plaintiffs to take nothing and the Defendant to go hence without day, with costs and fees, if any, to be assessed according to law.

(4) The Alternative *Rule 59* Motion for New Trial (Doc. 103) filed by Defendant Amin Radiology, Inc. d/b/a Citrus Diagnostic Center is DENIED.

¹⁶ The Court has carefully reviewed Amin's motion to dismiss and motion for summary judgment papers and notes that it never advanced, prior to trial and the Rule 50 motions, the condition of participation vs. condition of payment argument, nor did it point out the different certification requirements for employees of IDTFs vs. physician practice groups.

(5) The Clerk is directed to terminate all other pending motions, if any, and to close the file. /s/ Wm. Terrell Hodges

IT IS SO ORDERED.

UNITED STATES DISTRICT JUDGE

DONE and ORDERED at Ocala, Florida this 28th day of January, 2015.